

REMARKS

Claims 1-8, 10-20, 22-32 and 34-37 are now pending for prosecution in this case, of which Claims 28-32 and 34-37 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 9, 21 and 33 have been cancelled by Amendment herewith.

Support for the amendment to Claims 4 and 10 reciting the length of the nucleotide appears at least at page 3, lines 27-35 and lines 36-39 wherein the length of the encoded polypeptide and polynucleotide are described.

Support for the amendment to Claim 4 specifying that the hybridization occurs under stringent conditions occurs at least at page 3, lines 36-39.

Support for the amendments to Claims 4, 10 and 24 specifying the particular stringent hybridization conditions appears at least at page 9, line 41 to page 10, line 1.

Support for the amendments to Claims 5 and 6, deleting the terms "same mature" appears at least at page 3, lines 30-31.

Support for the amendment to Claim 22 clarifying the language to more precisely identify fragments of SEQ ID NO:2 appears at least at page 4, line 40 to page 5, line 2.

Support for the amendments to Claims 1, 4, 7, 9, 10, 19, 21, 22 and 24 appears at least in Example 11 and Figure 5.

Preliminary Matters and Objections

The Restriction of October 10, 2001 as well as Applicant's response of November 2, 2001 mention the election of Group I (Claims 1-27 and 33) as being directed to "polynucleotides, polypeptides, vectors, host cells and methods for producing polypeptides". However, Claim 33 is directed to an antagonist, and appears to be more properly grouped with Group III, and has been cancelled from the present application.

The Examiner has indicated that drawings are required to facilitate understanding of the invention. From the nature of the Examiner's communication, it appears that the formal drawings provided to the PCT Examining authority and which were filed with the present specification were somehow misplaced or not transmitted to the U.S.P.T.O.

Applicants hereby provide duplicate drawings consistent with the requirements of 37 CFR §1.81 *et seq.*

The Examiner has noted that the top margins of the specification are improper and has requested that a substitute specification be submitted with the correct margins.

Applicants hereby provide a Substitute Specification with corrected margins as well as corrections for various minor typographical errors.

The Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 4-6, 9-10, 21, 25-27 and 33 stand rejected under 35 U.S.C. § 112, Second Paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner has objected to the language of Claim 4 because of the language “comprising DNA hybridizing to the complement of . . .” allegedly is confusing because there is uncertainty whether the claimed nucleic acid is in a hybrid with “the complement of” or only capable of forming a hybrid with “the complement of”. Moreover, the Examiner has asserted that the term “hybridizing” is a relative term that does not indicate the degree of relatedness.

In response, Applicants have amended Claim 4 to specify that the claimed nucleic acid is capable of hybridizing to the reference sequence.

Claims 5 and 6 are rejected for containing the language “the same mature polypeptide” in that “mature”, while having an art recognized meaning as being a polypeptide that has completed all post-translational processing, is allegedly not defined by the specification and “same” is unclear in that it allegedly does not further define a limitation.

In light of the alleged confusion by the particular word choice, Applicants have amended the claim language in order to clarify that the reference sequence of the claim is the polypeptide expressed by the human cDNA of ATCC Dep. No. PTA-127.

Claims 9 and 21 are rejected for containing the language “scoring at least 80% positives”.

In response, the cancellation of Claims 9 and 21 has rendered the Examiner’s rejection moot.

Claims 4 and 24 are rejected for allegedly not precisely defining the specific conditions under which hybridization occurs.

In response, Applicants have modified the claims to specify more precise hybridization conditions.

Claim 22 is rejected for containing the phrase “or a fragment thereof”. The Examiner has graciously recommended a manner in which to obviate the rejection.

In response, Applicants have adopted the Examiner’s suggestion to render greater clarity to the claim.

Claims 25-27 stand rejected under 35 U.S.C. § 112, First Paragraph allegedly because the term “hSu(fu) polypeptide” is indefinite because there is no recitation in the specification of a material element or combination of elements that is unique and definitive of the term.

The claim was originally intended to mean, and the Examiner’s suggestion continues that meaning, that the second clause of the claim would be directed to antigenic fragments of SEQ ID NO:2.

Applicants respectfully request reconsideration and withdrawal of the above rejection.

The First Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1, 4, 7, 9-19, 21, 22, 24-27 stand rejected under 35 U.S.C. § 112, First Paragraph, as allegedly not being enabled by the specification for amino acid sequence variants of SEQ ID NO:2. Specifically, the Examiner has asserted that said variants are not enabled because there is no mention of a shared property amongst them or suggestion of which substitutions, deletions or insertions can be made to SEQ ID NO:2 that will preserve its structure and function.

In response, Applicants have amended to above claims to specify that the polypeptide of the subject claims bind to Gli. Example 11 demonstrates at least one biological activity of the hSu(fu) polypeptide and this activity has now been incorporated into the claims.

Applicants respectfully submit that the rejection has been improperly applied to Claim 22. This is true because the claim specifically and precisely identifies the claimed subject matter as the sequence of amino acid residues of SEQ ID NO:2 and antigenic fragments thereof. The art clearly recognizes that the language “fragment . . . sufficient to provide a binding site” clearly describes epitopic fragments. The generation of smaller fragments of a fully described and enabled full length sequence is well within the purview of one of ordinary skill and is in accord with established patent practice.

Applicants respectfully request reconsideration and withdrawal of the above rejection.

The Second Rejection under 35 U.S.C. § 112, First Paragraph

Claim 33 stands rejected under 35 U.S.C. § 112, First Paragraph, as allegedly containing subject matter that was not described in the specification in such a manner so as to enable one skilled to make or use the invention.

In response, the cancellation of Claim 33 renders the rejection moot.

The Third Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1, 4, 7, 9-19, 21, 22, 24-27 and 33 stand rejected under 35 U.S.C. § 112, First Paragraph, as allegedly containing subject matter that was not described in the specification in such a manner so as to reasonably convey to one skilled that the inventors has possession of the claimed invention.

Specifically, the Examiner has asserted that while the specification does describe the polynucleotide of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2, it allegedly does not describe polynucleotides and polypeptides within the full scope of the claimed degree of identity. The Examiner has asserted, however, that a sufficient description of the genus can be achieved by recitation of common structural features constituting a substantial portion of the genus. The

Examiner has further asserted that no activity defines the genus nor is such activity limiting of the claimed scope of the genus.

In response, Applicants have amended the relevant independent claims above to specify that the polypeptide of the subject claims bind to Gli. Example 11 demonstrates at least one biological activity of the hSu(fu) polypeptide and this activity has now been incorporated into the claims. The structural limitations of sequence identity in combination with the biological function of binding to Gli now clearly states possession of the entire scope of the claimed genus.

Applicants respectfully submit that the rejection has been improperly applied to Claim 22. This is true because the claim specifically and precisely identifies the claimed subject matter as the sequence of amino acid residues of SEQ ID NO:2 and antigenic fragments thereof. The art clearly recognizes that the language "fragment . . . sufficient to provide a binding site" clearly describes epitopic fragments. The generation of smaller fragments of a fully described and enabled full length sequence is well within the purview of one of ordinary skill and is in accord with established patent practice.

Applicants respectfully request reconsideration and withdrawal of the above rejection.

The Rejection under 35 U.S.C. § 102

Claims 4 and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by GenBank accession number AA061391, Marra *et al.*, 03 Feb. 1997 ("AA061391").

Specifically AA061391 is alleged to disclose an isolated nucleic acid molecule comprising DNA that is 94% identical to the instant SEQ ID NO:1 at positions 189 to 463, and would allegedly hybridize to a nucleotide comprising positions from about 74 to about 1372 of SEQ ID NO:1 (Claim 4), or be produced by hybridizing a test molecule under stringent conditions with a DNA molecule encoding a hSu(fu) polypeptide (Claim 10).

In response, Applicants have amended Claims 4 and 10 to recite that the claimed nucleotide sequence must have about 1299 nucleotides, whereas the prior art sequence only contains 275 nucleotides.

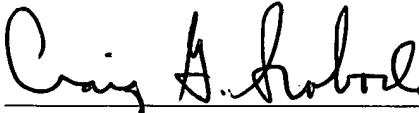
Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 4 and 10 under 35 U.S.C. § 102.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Applicants believe that this application is now in condition for immediate allowance and respectfully request that the outstanding objections and rejections be withdrawn and this case passed to issue.

The Examiner is highly encouraged to contact the undersigned at (650) 225-1489 in order to expedite the resolution of any remaining issues.

Respectfully submitted,
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PATENT TRADEMARK OFFICE

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 9, 21 and 33 have been cancelled.

Claims 1, 4-7, 10, 19, 22, 24 and 25 have been amended as follows:

1. (amended). Isolated nucleic acid comprising DNA having at least an 80% sequence identity to (a) a DNA molecule encoding a hSu(fu) polypeptide having the sequence of amino acid residues from 1 to 433 of Figure 1 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a); and wherein said hSu(fu) polypeptide binds Gli.

4. (amended). An isolated nucleic acid molecule having about 1299 nucleotides encoding a hSu(fu) polypeptide, comprising DNA capable of hybridizing under stringent conditons to the complement of the nucleic acid having the sequence of nucleotide positions from about 74 to about 1372 of Figures 6A-6B (SEQ ID NO:1); wherein said stringent conditions are 0.015 M sodium chloride/0.0015 M sodium citrate/0.1% sodium dodecyl sulfate at 50°C, and wherein said hSu(fu) polypeptide binds Gli..

5. (amended). An isolated nucleic acid molecule comprising DNA having at least an 80% sequence identity to (a) a DNA molecule encoding the ~~same mature~~ polypeptide encoded by the human protein cDNA in ATCC Deposit No. PTA-127 (DNA33455-1548), or (b) the complement of the DNA molecule of (a).

6. (amended). The isolated nucleic acid molecule of Claim 5 comprising DNA encoding the ~~same mature~~ polypeptide encoded by the human protein cDNA in ATCC Deposit No. PTA-127 (DNA33455-1548).

7. (amended). An isolated nucleic acid molecule comprising (a) DNA encoding a polypeptide having at least an 80% sequence identity to the sequence of amino acid residues from about 1 to about 433 of Figure 1 (SEQ ID NO:2), or (b) the complement of the DNA of (a), and wherein said polypeptide binds Gli..

10. (amended). — An isolated nucleic acid molecule having ~~at least 100~~ about 1299 nucleotides and produced by hybridizing a test DNA molecule under stringent conditions with (a) a DNA molecule encoding a hSu(fu) polypeptide having the sequence of amino acid residues from 1 to about 433 of Figure 1 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a), and, if the test DNA molecule has at least about an 80 % sequence identity to (a) or (b), isolating the test DNA molecule, and wherein said hSu(fu) polypeptide binds Gli.

19. (amended). — An isolated hSu(fu) polypeptide comprising a polypeptide having at least an 80% sequence identity to the sequence of amino acid residues from 1 to about 433 of Figure 2 (SEQ ID NO:2), and wherein said hSu(fu) polypeptide binds Gli.

22. (amended). — An isolated hSu(fu) polypeptide comprising the sequence of amino acid residues from 1 to about 433 of Figure 1 (SEQ ID NO:2), or a fragment ~~thereof~~ of said polypeptide sufficient to provide a binding site for an anti-hSu(fu) antibody.

24. (amended). — An isolated polypeptide produced by:
- (i) — hybridizing a test DNA molecule under stringent conditions with (a) a DNA molecule encoding a hSu(fu) polypeptide having the sequence of amino acid residues from 1 to about 433 of Figure 1 (SEQ ID NO:2), or (b) the complement of the DNA molecule of (a), and, if said test DNA molecule has at least about an 80% sequence identity to (a) or (b);
- (ii) ~~culturing~~ culturing a host cell comprising said test DNA molecule under conditions suitable for the expression of said polypeptide; and
- (iii) recovering said polypeptide from the cell culture,
wherein said stringent conditions are 0.015 M sodium chloride/0.0015 M sodium citrate/0.1% sodium dodecyl sulfate at 50°C, and
wherein said hSu(fu) polypeptide binds Gli..

25. (amended). — A chimeric molecule comprising ~~a~~ the hSu(fu) polypeptide of Claim 1 fused to a heterologous amino acid sequence.